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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,449

08/16/2006

Mariko Kuroda

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EXAMINER

ANDERSON, DENISE R

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

08/28/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No. 10/579,449	Applicant(s) KURODA ET AL.	
	Examiner Denise R. Anderson	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

2. By way of confirmation, the previous Office Action Summary indicated claim 1 was objected to and this was an error.

3. Claims 6 and 11-12 are objected to because of the following informalities: In line 2 of each claim, the term "over" should read "overall" to be in line with the specification, i.e. Table 2, second row. Similarly in line 2, the term "cm/mm" should read "cm/min" to be in line with the specification, i.e. Table 2, second row. Appropriate correction is required.

Claim Rejections - 35 USC § 102 Amended Claims

4. Claims 1-2 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited). Kim et al. discloses a membrane that is "usable in blood dialysis, plasma separation, etc." Kim et al., Abstract, lines 1-6. Kim et al. further teaches a hollow fiber membrane spun from a solution of aromatic polysulfone, polyvinyl pyrrolidone, and N-methyl-2-pyrrolidone – and the measured zeta potential of the hollow fiber is -1 at pH 7.4, using a 0.001 mol/l potassium chloride solution. Kim et al., Comparative Example 1 at ¶ 195 and in Table 1; ¶ 159.

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Independent claim 1 appears below in italics with the prior art and examiner's comments in normal font. The patentability analysis follows for dependant claims 2 and 6-7.

Claim 1. (Currently amended) A hollow fiber membrane (Kim et al., ¶ 195, line 17-18) for blood purification (Kim et al., Abstract, lines 1-6) having an integrally continuous structure (Kim et al., ¶ 195, the hollow fiber membrane was spun from a "homogeneous spinning solution" indicating an integrally continuous structure) from the inner membrane surface to the outer membrane surface, the membrane comprising a hydrophobic polymer (Kim et al., ¶ 195, lines 1-5, the hollow fiber membrane was spun from "aromatic polysulfone" which is a hydrophobic polymer) and a hydrophilic polymer (Kim et al., ¶ 195, lines 1-5, the hollow fiber membrane was spun from "polyvinyl pyrrolidone" which is a hydrophilic polymer), and exhibiting a zeta potential (Kim et al., Comparative Example 1 at ¶ 195 and in Table 1 where the measured zeta potential was -1 at a pH of 7.4; ¶ 158 where the zeta potential measurement was described and included using a 0.001 mole/l potassium chloride solution) on the inner surface thereof of greater than -3.0 mV but less than 0 mV at pH 7.5, when measured using a sample with an embedded resin on the outer side for allowing the electrolyte solution to flow through only the inside of the hollow fiber, and using a 0.001 mol/l potassium chloride aqueous solution as an electrolyte solution.

In summary, Kim et al. anticipates claim 1.

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5. Kim et al. anticipates claim 1 and further teaches a hollow fiber made from a polysulfone-based resin and a polyvinyl pyrrolidone. Kim et al., ¶ 195, lines 1-5, where the hollow fiber membrane was spun from "aromatic polysulfone" and "polyvinyl pyrrolidone." Kim et al. also teaches a dense layer thickness of 1 to 20 μm and this includes applicant's recited range of 1 to 5 μm in claim 7. Kim et al., ¶ 57, lines 5-7. In summary, Kim et al. anticipates claim 7.

6. With regards to the hollow fiber membrane properties recited in claims 2 and 6, Kim et al., in Table 1, further teaches an albumin sieving coefficient of 0.011 (1.1% versus the recited $< 0.6\%$) and a protein adsorption amount of 4.2 mg/m^2 (versus the recited $< 65 \text{ mg}/\text{m}^2$). Kim et al. also teaches that a "first object of the present invention" is to provide a hollow fiber membrane "that can separate a human serum albumin with a molecular weight of about 67,000 from proteins with a molecular weight in the range of 30,000-40,000." Kim et al., ¶ 19, lines 7-13; ¶ 6, lines 4-13. Thus, the Kim et al. hollow fiber membranes will remove more than 45% of a polyvinyl pyrrolidone with a weight average molecular weight of 40,000.

7. Kim fails to disclose the property limitations recited in claim 2, subparagraphs (d) and (e) which are the breaking strength and breaking elongation of the membrane. Kim also fails to disclose applicant's calculated – not measured – mass transfer coefficient shown in the Specification, ¶ 49 that applicant recites must be "0.040 cm/mm or greater" in claims 6 and 11-12. However, a membrane's properties are determined by its composition, and the polymer membrane of the reference has the same composition as the polymer membrane described by instant claims 1 and original claims 3 and 4. For

these reasons, the cited properties are presumed to be inherent to the membrane of the reference. See MPEP 2112. In summary, Kim et al. anticipates claims 2 and 6.

Claim Rejections - 35 USC § 103
Amended Claims

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited) as applied to 4 above, and further in view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002). Kozawa et al. discloses hollow fiber membranes formed from polysulfone-based resins and polyvinyl pyrrolidone for use in dialysis. Kozawa et al., Abstract, lines 1-8; Column 2, lines 48-52.

9. Kim et al. discloses the claimed invention except for a polyvinyl pyrrolidone membrane content of 3.0% to 5.0%. Kozawa et al. teaches that the hollow fiber membranes have a polyvinyl pyrrolidone content “in an amount of 3 to 15% by weight of the polysulfone,” which encompasses the 3.0% to 5.0 wt. % range recited in claim 5. Kozawa et al., Column 13, lines 63-66. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the Kim et al. membrane to have a 3.0% to 5.0% pyrrolidone membrane content, as taught by Kozawa et al., since Kozawa et al. states in the Abstract that such a modification would produce a membrane material “useful in dialysis.” Therefore, Kim et al., in view of Kozawa et al., discloses or suggests all claim 5 limitations.

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10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited) as applied to claim 1 above, and further in view of Carlsen et al. (US Patent No. Re. 36,914, Oct. 17, 2000). Carlsen et al. discloses a “dialysate filter” (applicant’s blood purification apparatus) that has “an asymmetric microporous, hollow fiber membrane.” Carlsen et al., Title, Figures 1 and 2.

11. With regards to claim 8, Carlsen et al., in Figure 2, discloses a cylindrical container with two nozzles (labeled “inlet port” and “outlet port”) for flow dialysate. Carlsen et al. further teaches a potting material to separate the hollow inside of the membrane from the outside of the membrane. Carlsen et al., Column 11, lines 30-32. Finally, in Figure 2, Carlsen et al. discloses a header cap at both ends of the apparatus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have installed the Kim et al. hollow fiber membranes into a blood purification apparatus, as taught by Carlsen et al., since Kim et al. states in the Abstract, lines 1-5 that the Kim et al. hollow fiber membranes are “usable in blood dialysis” and Carlsen et al states in the Title that the Carlsen et al. apparatus is a “dialysate filter” incorporating “hollow fiber membranes.” In summary, Kim et al., in view of Carlsen et al., discloses or suggests all claim 8 limitations.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited), in view of Carlsen et al. (US Patent No. Re. 36,914, Oct. 17, 2000), as applied to claim 8 above. Kim et al., in view of Carlsen et al.,

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discloses the claimed invention except for explicitly stating that the phosphorus clearance is 180 ml/min for a 1.5 m² membrane area. Because the structure of the Kim et al. hollow fiber membrane is the same as that recited by applicant and structure governs phosphorous clearance, the Kim et al. hollow fiber membrane in the Carlsen apparatus would exhibit the phosphorous clearance of 180 ml/min for a 1.5 m² membrane area. Thus, Kim et al., in view of Carlsen et al., discloses or suggests all claim 9 limitations.

13. As an aside, Kozawa et al. (US Patent No. 6,355,730 B1) discloses a method to calculate both phosphorus clearance [claim 9] and overall mass transfer coefficients [claims 6 and 11-12] in the context of, "Membrane materials for removing uremic toxins from a hydrophobic polymer such as polysulfone and two polyvinyl pyrrolidones, hydrophilic polymers of different molecular weights, that is 10-50 wt. % of a low molecular weight component (molecular weight < 100,000) and 90-50 wt. % of a high molecular weight component (molecular weight \geq 100,000). The membranes are permselective useful in dialysis." Kozawa et al., Abstract, lines 1-8. Unfortunately, the Kozawa et al. clearance calculation was different from that of applicant and there is not enough data to put the two calculations on the same basis. Kozawa et al., Column 7, lines 49-66. Applicant's Specification, ¶¶ 49-55. Similarly, since the overall mass transfer calculation is based on the clearance calculation, there is not enough data to put applicant's calculation on the same basis with that of Kozawa et al.

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14. Because calculations of phosphorus clearance and overall mass transfer coefficients are different between applicant and Kozawa et al., the examiner will continue to make the argument that the structure of the Kim et al. hollow fiber membrane is the same as that recited by applicant. Since the structure governs phosphorous clearance or the overall mass transfer coefficient, the Kim et al. hollow fiber membrane would exhibit the phosphorous clearance or overall mass transfer coefficient recited in the claim.

Claim Rejections - New Claims

15. New claims 10-20 recite various combinations of previous claims. A table lists the claim combinations below, along with the prior art that the claim reads on.

New Claim	Claim Combination	Prior Art Rejection
Claim 10	Claim 2 + Claim 5	Kim et al., in view of Kozawa et al.
Claim 11	Claim 2	Kim et al.
Claim 12	Claim 2 + Claim 5	Kim et al., in view of Kozawa et al.
Claim 13	Claim 2 + Claim 7	Kim et al.
Claim 14	Claim 5 + Claim 7	Kim et al., in view of Kozawa et al.
Claim 15	Claim 6 + Claim 7	Kim et al.
Claim 16	Claim 2 + Claim 8	Kim et al., in view of Carlsen et al.
Claim 17	Claim 5 + Claim 8	Kim et al., in view of Kozawa et al., in view of Carlsen et al.
Claim 18	Claim 6 + Claim 8	Kim et al., in view of Carlsen et al.
Claim 19	Claim 7 + Claim 8	Kim et al., in view of Carlsen et al.
Claim 20	Claim 2 + Claim 8 + Claim 9	Kim et al., in view of Carlsen et al.

The results of the above table are summarized below.

16. Claims 11, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited).

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17. Claims 10, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited), in view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002).

18. Claims 16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited), in view of Carlsen et al. (US Patent No. Re. 36,914, Oct. 17, 2000).

19. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited), in view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002), and in further view of Carlsen et al. (US Patent No. Re. 36,914, Oct. 17, 2000).

Response to Arguments

20. Applicant's arguments filed June 16, 2008 have been fully considered but they are not persuasive. Applicant states that they made the Example 1 polymer fiber of Kim et al., except for three changes.

(1) Applicant substituted Kim's solvent of N-methyl-2-pyrrolidone for dimethyl acetamide in order to get the polyvinyl pyrrolidone into the recited range of 3.0% to 5.0% of dependent claim 5. Applicant's Response, June 16, 2008, Page 10, lines 4-8.

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(2) The Kim et al. hollow fiber was made with "polyvinyl pyrrolidone of unknown molecular weight" and applicant did not state how this issue was handled experimentally. Applicant's Response, Page 9, Section entitled "Difference in Membrane Structure," lines 6-8.

(3) The zeta-potential was measured differently, i.e. the "zeta potential . . . was measured having an embedded resin on the outer side of the membrane" and, presumably, Kim et al. did not embed the fiber in resin. Applicant's Response, Section entitled Declaration under 37 C.F.R. 1.132, lines 2-4.

Applicant measured the zeta potential of this fiber to be +4.0 and not the -1.0 zeta potential shown by Kim et al. in Table 1, Comparative Example 1, last column.

Applicant's Response, Section entitled Declaration under 37 C.F.R. 1.132, lines 2-4.

The +4.0 zeta potential is outside applicant's claimed range of -3.0 to 0.0 and applicant asserts that Kim et al. does not anticipate applicant's claimed hollow fiber membrane.

21. The examiner's response is that the one data point lacks at least a control and also a replicate. From the one data point, it is unknown how much each of the three changes, plus experimental error, contributed to the move from a -1.0 zeta potential to a +4.0 zeta potential. In order to move the prosecution along, the examiner will maintain the previous claim 1 rejection where the zeta potential limitation is addressed.

22. To summarize the claim 1 patentability analysis, Kim et al. discloses a membrane that is "usable in blood dialysis, plasma separation, etc." Kim et al., Abstract, lines 1-6. Kim et al. further teaches a hollow fiber membrane spun from a solution of aromatic polysulfone, polyvinyl pyrrolidone, and N-methyl-2-pyrrolidone – and the measured zeta

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potential of the hollow fiber was -1 at pH 7.4, using a 0.001 mol/l potassium chloride solution. Kim et al., Comparative Example 1 at ¶ 195 and in Table 1; ¶ 159. As such, Kim et al. anticipates claim 1.

23. Applicant also states that Kim's solvent of N-methyl-2-pyrrolidone needs to be substituted with dimethyl acetamide in order to get the polyvinyl pyrrolidone into the recited range of 3.0% to 5.0% of dependent claim 5. Applicant's Response, June 16, 2008, Page 10, lines 4-8. The examiner used a second reference to address the 3.0% to 5.0% polyvinyl pyrrolidone limitation. From the above patentability analysis, claim 5 was rejected under 103(a) over Kim et al., in view of Kozawa et al..

24. Regarding claim 5, it was stated above that Kim et al. discloses the claimed invention except for a polyvinyl pyrrolidone membrane content of 3.0% to 5.0%.

Kozawa et al. teaches that the hollow fiber membranes have a polyvinyl pyrrolidone content "in an amount of 3 to 15% by weight of the polysulfone," which encompasses the 3.0% to 5.0 wt. % range recited in claim 5. Kozawa et al., Column 13, lines 63-66.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the Kim et al. membrane to have a 3.0% to 5.0% pyrrolidone membrane content, as taught by Kozawa et al., since Kozawa et al. states in the Abstract that such a modification would produce a membrane material "useful in dialysis." Therefore, Kim et al., in view of Kozawa et al., discloses or suggests all claim 5 limitations.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

26. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise R. Anderson whose telephone number is (571)270-3166. The examiner can normally be reached on Monday through Thursday, from 8:00 am to 6:00 pm.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter D. Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DRA

/Walter D. Griffin/

Supervisory Patent Examiner, Art Unit 1797